IN THE CIRCUIT COURT OF MONTGOMERY COUNTY, ALABAMA

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STATE OF ALABAMA,).	200
Plaintiff,)))	
v.) Civil Action No. 2005-219	72
BAYER LABORATORIES, INC., et al.,)	ယ္က မိ်္မ္ပါ လ
Defendants.)	(3)

BAYER'S AMENDED ANSWER TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Bayer Corporation ("Bayer Corp."), Bayer Pharmaceuticals Corporation ("Bayer Pharm."), and Bayer HealthCare, LLC ("Bayer HealthCare," and collectively with Bayer Corp. and Bayer Pharm., "Bayer") by their undersigned counsel, hereby file their Amended Answers and Affirmative Defenses to Plaintiff State of Alabama's Second Amended Complaint (the "Complaint").

PREFACE

The State of Alabama's ("Plaintiff," the "State," or "Alabama") claims are precluded by the Settlement Agreement it entered into with Bayer in 2001 covering the very claims of AWP inflation at issue in this case. Indeed, the State has acknowledged in its pleadings before this Court that the 2001 Settlement Agreement substantially precludes the claims set forth in the Complaint against Bayer. (See Pl.'s Opp'n to Bayer's Mot. to Dismiss 1–2; filed Apr. 6, 2006.) And despite having been directed by the Court to "fix up" its First Amended Complaint to reflect the 2001 Settlement

¹ Unless otherwise specified, admissions and denials by "Bayer" below are made by each of Bayer Corp., Bayer Pharm., and Bayer HealthCare.

Agreement, the State's Second Amended Complaint contains precisely the same precluded claims. (Sept. 30, 2005 Tr. at 60; Ex. A to Bayer's June 23, 2006 Notice of Supp'l Authority.)

The Complaint improperly and repetitively refers to Bayer and certain other Defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Bayer or other Defendants or third parties. Intentionally ambiguous pleading is improper and insufficient to apprise Bayer in any meaningful sense of the allegations asserted against it. Bayer nevertheless attempts to respond to Plaintiff's allegations to the extent possible under the circumstances.

In answering the Complaint, Bayer responds for itself only, even when Plaintiff's allegations refer to alleged conduct by Bayer and other persons or entities. To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of persons, entities or Defendants other than Bayer, Bayer is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies those allegations.

The Complaint also improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the Complaint's allegations are vague or conclusory. The Complaint also includes terms which are undefined and which are susceptible of different meanings, and is therefore ambiguous.

Bayer specifically denies the existence of, or its participation in any fraud, fraudulent scheme, fraudulent suppression, concealment, conspiracy or any other

wrongdoing. Bayer further denies each and every allegation contained in the Complaint, except as specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes or speculations which are contained in any averment or in the Complaint as a whole. Moreover, Bayer specifically denies any allegations contained in headings, footnotes or unnumbered paragraphs in the Complaint. Bayer also denies all allegations that contain legal arguments and conclusions of law as those allegations do not require a response.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

INTRODUCTION

- 1. Denied. Bayer denies the allegations in Paragraph 1 with respect to Bayer, and is without knowledge sufficient to form a belief as to the truth or falsity of the allegations made in Paragraph 1 with respect to the remaining Defendants, and therefore Bayer denies these allegations. Bayer denies any remaining allegations in Paragraph 1.
- 2. Denied. To extent they relate to Bayer, Bayer denies the allegations in paragraph 2 concerning the "fraudulent pricing scheme," denies the existence of any such scheme, and denies that any "action" is "require[d] to ensure fair dealing between [Bayer] and the State." Bayer is without knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 2, and therefore Bayer denies them.
- 3. Admitted in part, denied in part. Bayer admits only that the State of Alabama purports to bring this action, and that Plaintiff's Complaint speaks for itself.

Bayer denies that Plaintiff has standing to bring this action or is entitled to any relief. Bayer specifically denies that it engaged in a "drug-pricing scheme" and that it engaged in any "improper" or "unlawful" actions. Bayer is without knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 3 with respect to the remaining Defendants, and therefore Bayer denies any remaining allegations in Paragraph 3.

4. Admitted in part, denied in part. Bayer admits only that the State of Alabama purports to bring this action. Bayer denies that there is any basis which permits Alabama to bring this action, and otherwise has neither knowledge nor information sufficient to form a belief as to the truth of the allegations set forth therein.

PARTIES

- 5. Admitted in part, denied in part. Bayer admits that the State of Alabama purports to bring this action in its capacity as sovereign and on behalf of the Alabama Medicaid Agency. Bayer specifically denies that Plaintiff has standing to bring this action or is entitled to any relief.
- 6. Denied. To the extent that the allegations in this paragraph refer to statutes and regulations, those sources speak for themselves, and any characterizations thereof are denied. Bayer specifically denies that the State of Alabama has asserted proper claims against Bayer in this action or that any relief is appropriate.
- 7-27. Denied. Paragraphs 7-27 are directed to Defendants other than Bayer and thus require no response from Bayer. To the extent the allegations in paragraphs 7-27 are deemed to include allegations against Bayer, Bayer is without knowledge or information sufficient to form a belief as to the truthfulness of the allegations contained in these paragraphs. These allegations are, therefore, denied.

- 28. Admitted. Bayer admits that Bayer Corp. is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania. Bayer admits that Bayer Corp. is a successor to Miles, Inc. Bayer also admits that Bayer Corp. is a wholly-owned United States subsidiary of Bayer AG, a German corporation with its principal place of business located at 51368 Leverkusen, Germany.
- 29. Admitted. Bayer admits that Bayer Pharm. is a Delaware corporation with an address at 400 Morgan Lane, West Haven, Connecticut, and its principal place of business in Connecticut.
- 30. Admitted. Bayer admits that Bayer HealthCare is a legally independent company with five divisions operating under the Bayer AG umbrella. Bayer admits that Bayer HealthCare is a Delaware limited liability company with an address at 511 Benedict Avenue, Tarrytown, New York. Bayer further admits that Bayer HealthCare has its principal place of business in New York.
- 31. Admitted in part; denied in part. In 2001, Plaintiff the State of Alabama released any claim against Bayer regarding Koate, Kogenate, Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III. No response is required as to allegations concerning such dismissed claims. Further, this paragraph lumps Defendants Bayer Corp., Bayer Pharm., and Bayer HealthCare together as "Bayer Defendants," even though they are separate legal entities and are sued as separate Defendants. Nonetheless, Bayer admits that at times relevant to this litigation Bayer Corp., Bayer Pharm., and Bayer HealthCare were diversified health care companies whose business included the

development, manufacture, marketing, sale, and/or distribution of health care products and services, including pharmaceuticals. Bayer admits that, at some point in time, Bayer Corp., Bayer Pharm., or Bayer HealthCare, or their respective subsidiaries, either manufactured, distributed, marketed, or sold the following pharmaceuticals: Adalat, Adalat CC, Avelox, Baycol, Cipro, Cipro IV, Cipro XR, Gamimune N, Gamunex, Koate-DVI, Koate-HP, Kogenate, Kogenate FS, Mycelex, Precose, and Prolastin. By way of further response, Bayer admits that, at some point in time, Alabama Medicaid reimbursed providers for the foregoing drugs.

32-94. Denied. Paragraphs 32-94 are directed to Defendants other than Bayer and thus require no response from Bayer. To the extent the allegations in paragraphs 32-94 are deemed to include allegations against Bayer, Bayer is without knowledge or information sufficient to form a belief as to the truthfulness of the allegations contained in these paragraphs. These allegations are, therefore, denied.

JURISDICTION AND VENUE

- 95. Denied.
- 96. Admitted in part, denied in part. Bayer admits the allegations set forth in this paragraph as to Bayer, but does not have knowledge sufficient to form a belief as to the truth or falsity of the allegations concerning the remaining Defendants, and therefore Bayer denies any remaining allegations.
- 97. Denied. The allegations contained in this paragraph state legal arguments and conclusions of law to which no response is required. By way of further answer, to the extent the allegations reference statutes or regulations, those sources speak for themselves and any characterizations thereof are denied. To the extent that Bayer is required to

respond, Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and those allegations are therefore denied.

FACTUAL BACKGROUND

- 98. Admitted in part, denied in part. Bayer admits that the Alabama Medicaid Program is a state-administered program with federal matching funds which pays for medical care, including prescription drug benefits, for certain Alabama citizens. Bayer denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in this paragraph. The remaining allegations are, therefore, denied.
- 99. Denied. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in this paragraph. The allegations are, therefore, denied.
- 100. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer. To the extent the allegations are directed to other Defendants, Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies them.
 - 101. Admitted.
- 102. Denied. To the extent that the allegations in this paragraph refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Bayer denies that Plaintiff's selective characterization of those statutes and regulations is necessarily complete or accurate, and therefore denies them. Bayer denies any remaining allegations.

- 103. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. The remaining allegations are, therefore, denied,
- 104. Denied. Bayer denies knowledge or information sufficient to form a belief about the truth of the allegations set forth in this paragraph. The allegations are, therefore, denied.
- 105. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and denies the remaining allegations because it lacks knowledge or information sufficient to form a belief as to their truth.
- as to Bayer. Bayer specifically denies the allegation that the State of Alabama "is not privy to the actual market prices which it can then compare against the reported prices" for Bayer drugs. Indeed, pursuant to their 2001 Settlement Agreement, Bayer has provided Plaintiff the State Alabama quarterly average sale prices ("ASP") for all Bayer drugs since early 2001. The State can readily compare these ASPs to AWP, WAC, and Direct Prices for Bayer drugs. To the extent that remaining allegations are directed to other Defendants, Bayer is without sufficient knowledge or information to form a belief as to their truth and, therefore, denies them.
- 107. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer. Bayer specifically denies that it failed to disclose relevant discounts, rebates or other inducements to purchase its drugs. In particular, Bayer's quarterly ASP reports

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to the Plaintiff were inclusive of all relevant discounts, rebates, and other inducements. With respect to any remaining allegations, Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. remaining allegations are, therefore, denied.

- Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations directed at other Defendants, and therefore Bayer denies them.
- Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. The remaining allegations are, therefore, denied.
- Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. The remaining allegations are, therefore, denied.
- Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. The remaining allegations are, therefore, denied.
- Admitted in part, denied in part. Bayer denies each and every allegation set forth in this paragraph as to Bayer, except admits that other plaintiffs have filed complaints alleging similarly meritless and ill-informed claims against Bayer from which

Plaintiff here appears to have largely copied its allegations. Bayer also admits that Bayer is a party to litigation related to Medicaid drug reimbursement. Except as specifically admitted, Bayer denies each and every allegation in this paragraph.

- 113. Admitted in part, denied in part. Bayer admits that it is a party to litigation filed by New York City. The remaining allegations contained in paragraph 113 are legal arguments and conclusions of law to which no response is required. To the extent Bayer is required to respond to these allegations, Bayer denies that the State has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to Bayer. Bayer denies any remaining allegations in paragraph 113.
- Admitted in part, denied in part. Bayer has insufficient information or knowledge to form a belief as to the truth of the allegations directed at other Defendants, and therefore Bayer denies them. To the extent allegations in this paragraph are directed to Bayer, Bayer admits only that in April 2003 Bayer Corp. pled guilty to a one-count Information alleging that Bayer Corp, failed to list particular drugs with the Food and Drug Administration in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. By way of further response, Bayer states that it entered into a settlement covering these claims with federal and state governments, including Alabama, pursuant to which Bayer paid approximately \$3,004,185.17. In exchange, Alabama and other government agencies released all claims against Bayer related to the drugs that were the subject of the suit. Bayer denies any remaining allegations.

- 115. Admitted in part, denied in part. Bayer admits only that in 2001 Bayer reached a settlement agreement with federal and state governments, including Alabama, of the claims at issue in this case related to Koate and Kogenate, as well as Konyne-80, Gamimune N 5%, Gamimune N 10%, and Thrombate III. By the 2001 Settlement Agreement, the governments, including Alabama, released all claims related to the subject drugs in exchange for Bayer's payment of \$14 million, of which \$83,759.46 was allocated to Alabama. As a further answer, Bayer admits that in 2003 Bayer Corp. pled guilty to a one-count Information alleging that Bayer failed to list particular drugs with the Food and Drug Administration in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. Bayer states further that it entered into a settlement covering these claims with federal and state governments, including Alabama, pursuant to which Bayer paid Alabama approximately \$3,004,185.17. In exchange, Alabama and other government agencies released all claims against Bayer related to the drugs that were the subject of the suit. Bayer denies any remaining allegations.
- 116. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 117. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth

in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

- 118. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 119. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 120. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 121. Denied. To the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer. Bayer denies knowledge or information sufficient to form a belief as to the truth of the allegations directed to other Defendants and, therefore, denies them.

- 122. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 123. Denied. This paragraph appears to contain no allegations as to, or relevant to, any claims against Bayer and therefore requires no answer; to the extent Plaintiff purports to make allegations as to Bayer, Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- Bayer. In particular, Bayer states that, at least since early 2001, Alabama has received accurate average sale price reports, net of all relevant discounts, for all drugs Bayer marketed during each quarter. To the extent the allegations in this paragraph are direct to other Defendants, Bayer does not have knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies them.
- 125. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations therein, and affirmatively states that if there were any merit to the claims alleged herein as to Bayer, it would neither be impractical nor impossible for the Plaintiff to allege specifically its claims as to Bayer, which Plaintiff has entirely failed to do.

126. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

CLAIMS

COUNT ONE—FRAUDULENT MISREPRESENTATION

- 127. Bayer repeats and incorporates by reference its responses to numbered paragraphs 1 through 126 above.
- 128. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 129. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 130. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

COUNT TWO—FRAUDULENT SUPPRESSION

- 131. Bayer repeats and incorporates by reference its responses to paragraphs 1 through 130 above.
- 132–39. The Complaint did not contain paragraphs numbered 132–39. Therefore no response from Bayer is required.

- 140. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 141. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 142. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

COUNT THREE—WANTONNESS

- 143. Bayer repeats and incorporates by reference its responses to paragraphs 1 through 142 above.
- 144. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 145. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 146. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

147. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

COUNT FOUR—UNJUST ENRICHMENT

- 148. Bayer repeats and incorporates by reference its responses to numbered paragraphs 1 through 147 above.
- 149. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 150. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 151. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.
- 152. Denied. Bayer denies each and every allegation set forth in this paragraph as to Bayer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

PRAYER FOR RELIEF

Bayer denies that Plaintiff is entitled to a judgment or any other relief requested in their section entitled "PRAYER FOR RELIEF" and unnumbered "WHEREFORE" paragraph following paragraph 152 of the Complaint.

JURY DEMAND

Bayer denies that the State has asserted any viable claims that would necessitate trial by jury.

BAYER AFFIRMATIVE DEFENSES

By alleging the matters set forth below, Bayer does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that Plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, Bayer incorporates its answers to paragraphs 1–152 above, and further alleges as follows:

First Defense

The State fails to state a claim against Bayer upon which relief may be granted.

Second Defense

The State's claims are barred, in whole or in part, because the State has released, settled, entered into an accord and satisfaction, and otherwise compromised its claims.

Third Defense

The State's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Fourth Defense

The State's claims are barred, in whole or in part, by the filed rate doctrine.

Fifth Defense

The State has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Bayer as alleged.

Sixth Defense

To the extent the State obtains recovery in any other case predicated on the same factual allegations, the State is barred from seeking recovery against Bayer pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

Seventh Defense

The State's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Alabama and any other States whose laws are or become relevant in the course of this litigation.

Eighth Defense

The State's claims are barred, in whole or in part, by the Noerr-Pennington doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Bayer in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Ninth Defense

Any and all actions taken by Bayer with respect to any of the matters alleged were taken in good faith and in accordance with established industry practice.

Tenth Defense

Alabama's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

The State's claims are preempted by the Commerce Clause of the United States Constitution.

Twelfth Defense

The State's claims against Bayer are barred because Bayer has compiled with all applicable regulations of the federal and state governments.

Thirteenth Defense

The State's claims against Bayer are barred, in whole or in part, by the applicable statutes of limitations and repose and by the doctrines of laches, estoppel, and waiver.

Fourteenth Defense

The State's claims are barred, in whole or in part, because they violate Bayer's rights under the *Due Process* and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as the State seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Fifteenth Defense

The State's claims are barred because Bayer's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by the State.

Sixteenth Defense

The State fails to state with particularity facts to support its claims, including without limitation its claims of fraudulent misrepresentation and fraudulent concealment.

Seventeenth Defense

The State's claims against Bayer are barred, in whole or in part, because Bayer did not make any false statements to the State or any of its citizens. As to any statement asserted against Bayer that the State alleges to be false or misleading, Bayer had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Eighteenth Defense

To the extent that the State attempts to seek equitable relief against Bayer, it is not entitled to such relief because the State has an adequate remedy at law.

Nineteenth Defense

The State lacks standing to bring some or all of the claims in this suit.

Twentieth Defense

The State did not rely on the allegedly fraudulent statements or conduct of Bayer as required for the State to prevail on its claims.

Twenty-First Defense

The State's claims against Bayer under the various state statues are barred in whole or in part to the extent those statutes do not govern conduct that is predominantly interstate in nature.

Twenty-Second Defense

To the extent the State seeks injunctive relief against Bayer, such claims were mooted by the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Twenty-Third Defense

Document 63

To the extent the State seeks injunctive relief against Bayer, such claims are barred by the doctrines of in pari delicto and/or unclean hands.

Twenty-Fourth Defense

Any claims brought on behalf of third party payers against Bayer are barred, in whole or part, with respect to any alleged overcharge or on the ground that third party payers passed on any effect of the alleged inflated prices to their customers or employees in the form of higher premiums.

Twenty-Fifth Defense

The State's claims against Bayer are barred, in whole or in part, with respect to any alleged overcharge because such overcharge, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed on to the State.

Twenty-Sixth Defense

The State's claims against Bayer are barred, in whole or in part, due to its failure to join indispensable parties.

Twenty-Seventh Defense

The State's claims against Bayer are barred, in whole or in part, because it has suffered no damages.

The State's claims are barred, in whole or in part, because any injuries sustained by the State were the result of its own conduct or the intervening or superseding conduct of third parties.

Twenty-Ninth Defense

The State's claims are barred, in whole or in part, because some or all of the State's claims arise from its failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

Thirtieth Defense

The State's claims against Bayer for damages are barred, in whole or in part: (1) because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Bayer; (2) because it would be unjustly enriched if allowed to recover; (3) by the doctrine of consent and/or ratification to the extent that the State has received and paid for medicines manufactured, marketed and sold by Bayer or its affiliates after the filing of the State's original Complaint; and (4) because any purported damages are speculative and remote and because of the impossibility of ascertaining and allocating the damages.

Thirty-First Defense

Bayer is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by the State with respect to the same injuries.

Thirty-Second Defense

Any damages recovered by the State from Bayer must be limited by the applicable statutory ceilings on recoverable damages, including without limitation Alabama Code 6–11–21.

Thirty-Third Defense

The State fails to allege facts or a cause of action against Bayer sufficient to support a claim for attorneys' fees, treble damages, and/or legal fees.

Thirty-Fourth Defense

To the extent punitive damages are sought, the State's punitive damages claims against Bayer: (1) have no basis in law or fact; (2) are not recoverable because the allegations are legally insufficient to support a claim for punitive damages against Bayer; and (3) cannot be sustained because: (i) laws regarding the standards for determining liability for and the amount of punitive damages fail to give Bayer prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Bayer's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the constitutions of any applicable states' laws; (ii) an award of punitive damages would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, statutes, and public policy of any applicable states' laws; (iii) an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Bayer for punitive damages arising

from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Bayer's medicines would constitute impermissible multiple punishments for the same wrong, in violation of Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law, and statutory law of any applicable states' laws; (iv) any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable states' law; and (v) any award of punitive damages, which are penal in nature, without according Bayer the same protections that are accorded to all criminal Defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Bayer's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable states' laws.

Thirty-Fifth Defense

To the extent punitive damages are sought, the State's claim for punitive damages against Bayer cannot be sustained because an award of punitive damages by a jury that:

(1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Bayer: (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding the State's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law, and public policies of any applicable states' laws.

Thirty-Sixth Defense

To the extent punitive damages are sought, the State's claim for punitive damages against Bayer cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Bayer's

due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Bayer's right not to be subject to an excessive award; and (3) be improper under the constitutions, common law, and public policies of any applicable states' laws.

Thirty-Seventh Defense

Plaintiff's claims for punitive damages are barred by Alabama Code § 6–11–21, which prohibits the State from recovering punitive damages.

Thirty-Eighth Defense

Plaintiff's unjust enrichment claims are barred, in whole or in part, because Bayer did not retain any money belonging to the State as a result of any alleged overpayments as required under Alabama law.

Thirty-Ninth Defense

Bayer hereby gives notice that it intends to rely upon any additional defense that is now or may become available or appear during or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Bayer also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than Alabama.

Fortieth Defense

Bayer adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

WHEREFORE, Bayer prays that this Court:

- 1. Dismiss the State of Alabama's Second Amended Complaint with prejudice and enter judgment in its favor and against the State;
- 2. Award Bayer its costs and expenses; and
- 3. Grant such other and further relief as this Court deems just and proper.

Respectfully submitted this 25 day of July, 2006.

Fred M. Hash by R.E.P. (POUCO 6)

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CERTIFICATE OF SERVICE

I, Fred M. Haston, hereby certify that I have on this 25th day of July, 2006, electronically served a true and correct copy of the foregoing Amended Answer to Plaintiff's Second Amended Complaint on counsel of record by transmission to LexisNexis File & Serve LNFS, pursuant to Case Management Order No. 2.

Fred M. Yeston by R.E.D. (PONOS6)

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